

MAR - 4 2004

K032454

## **510(k) Summary**

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### **SUBMITTER:**

#### **Submitted on behalf of:**

**Company Name:** Bio-Lok International Inc.  
**Address:** 312 South Military Trail  
Deerfield Beach, FL 33442  
**Telephone:** (954) 698-9998  
**Fax:** (954) 698-9925

**by:** Elaine Duncan, M.S.M.E., RAC  
President, Paladin Medical, Inc.  
PO Box 560  
Stillwater, MN 55082  
**Telephone:** 715-549-6035  
**Fax:** 715-549-5380

**CONTACT PERSON:** Elaine Duncan

**DATE PREPARED:** August 7, 2003

**TRADE NAME:** Silhouette™ & Silhouette™ IC dental implant system with  
Laser-Lok™ surface treatment

**COMMON NAME:** Dental implant, Endosseous

**SUBSTANTIALLY EQUIVALENT TO:** Silhouette™ and Silhouette™ IC dental implants with Laser-Lok™ surface treatment are substantially equivalent to Micro-Lok™ implants [see manufacturer's various predicate 510(k)'s]. Additional substantially equivalent predicate devices with predicate mechanical and physical features are the Astra Tech Fixture ST, Osseotite NT from 3I, and Frialit-2 by Dentsply Friadent Ceramed.

**DESCRIPTION of the DEVICE:** The Silhouette™ (hex-top) and Silhouette™ IC (internal connection) incorporate a self-tapping tapered implant design that provides lateral compression of the osteotomy site to greatly improve primary stability. The reverse buttress type thread is flat in the lower supporting plane of the thread, passing compression forces to the bone and eliminating shear forces common to symmetrical "V" type thread implants. The screw thread portion of the implants are surfaced roughened with Osseo-Lok™ per Bio-Coat, Inc. specifications. Laser-Lok™ is a surface technology in which two laser generated patterns of microscopic grooves are applied to the collar of the implant to engineer the biological width and tissue attachment.

**INDICATIONS FOR USE:** The implant is designed for use in edentulous sites for support of complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework or partial dentures, or a single tooth replacement, overdenture, or hybrid denture.

**SUMMARY of TESTING:** The Laser-Lok surface treatment does not introduce new issues for biocompatibility as documented in a summary of all testing conducted to-date. Mechanical testing was done in accordance with the FDA guidance "Information for premarket notification submissions for screw-type endosseous implants" issued on December 9, 1996. Results from an independent laboratory showed the Silhouette™ and Silhouette™ IC with Laser-Lok™ surface treatment to have sufficient mechanical static and dynamic strength. Additional test reports include finite element analysis, animal and clinical testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR - 4 2004

Biolock International, Incorporated  
Ms. Elaine Duncan  
President  
Paladin Medical, Incorporated  
P.O. Box 560  
Stillwater, Minnesota 55082-0560

Re: K032454

Trade/Device Name: Bio-Lok International, Incorporated Silhouette™ and Silhouette  
™ IC Endosseous Implant  
Regulation Number: 872.3640  
Regulation Name: Endosseous Implant  
Regulatory Class: III  
Product Code: DZE, NHA  
Dated: December 10, 2003  
Received: December 11, 2003

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

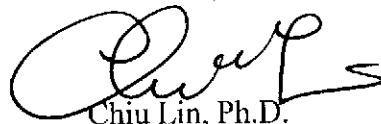
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known) K032454

Device Name: **Bio-Lok International, Inc. Silhouette™ and Silhouette™ IC endosseous implant**

Indications for Use:

The implant is designed for use in edentulous sites for support of complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework or partial dentures, or a single tooth replacement, overdenture, or hybrid denture.

**(Please Do Not Write Below This Line-Continue On Another Page If Needed)**  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

Suzanne Rums  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K032454